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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,103	10/16/2006	John C. Bell	18041B-PCTUS	1653

7590  
Legal Department  
930 Clopper Road  
Gaithersburg, MD 20878

EXAMINER
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MOSHER, MARY

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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01/23/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,103	<b>Applicant(s)</b> BELL ET AL.	
	<b>Examiner</b> Mary E. Mosher	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3-6 and 8-20 is/are pending in the application.
- 4a) Of the above claim(s) 16-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-6, 8-15 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claims 16-19 drawn to an invention nonelected with traverse in the reply filed on 11/2/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Objections***

Claim 4 remains objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form, for reasons of record. Applicant argues that claim 4 requires an additional mutation selected from those the Markush group. However, the claim recites "comprising one or more mutations...selected from the group consisting of..." It does not recite "comprising one or more *additional* mutations..." or "*further* comprising one or more mutations..." Therefore, it is maintained that claim 4 encompasses mutant VSV with M mutations such as V221F, without the  $\Delta$ M51 mutation required in parent claim 3.

### ***Claim Rejections - 35 USC § 103***

Claims 3-5, 9-15, and 20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Whitt et al US2005/0260601, for reasons of record. The difference in disclosure between the published application and the priority document is noted; the

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examiner agrees that only the information found in Whitt's priority document is available as prior art.

Applicant argues no reasonable expectation of success, citing Lichty et al regarding the inability of one skilled in the art to obtain VSV viruses bearing particular mutations. However, in Whitt's priority document, there is a working example of a VSV mutant with a substitution mutation at position 51, see page 12 of provisional application 60408988. The ability of Whitt to successfully make a substitution mutation at position 51 reasonably suggested that position 51 is nonessential, and provided a reasonable expectation of success for a deletion mutation at position 51.

Applicant further argues unexpected results, that Whitt teaches that the M mutation renders viruses non-cytopathic, while claimed mutation demonstrates oncolytic and cytopathic properties. Applicant is requested to point to the data comparing the cytopathogenicity of the  $\Delta$ M51 mutant to that of an M51 substitution mutant comparable to the mutant in Whitt. The examiner understands that the instant application teaches an oncolytic property for  $\Delta$ M51 and M51 substitution mutants (that is, the mutant virus is cytopathic *in cancer cells*). The examiner also understands that the Whitt priority document does not teach an oncolytic property. However, the fact pattern here is similar to In re Dillon (16 USPQ2d 1897, 919 F2d688, CAFC 1990). Applicant's discovery that the claimed  $\Delta$ M51 mutation has an oncolytic property not disclosed for the prior art does not alone defeat the prima facie case. Whitt teaches a useful M51 substitution mutant for a gene vector, and suggests a partial deletion mutant. It would have been readily apparent to the ordinary artisan that the deletion mutant would be useful for the same

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gene vector purposes. It was common knowledge in the art that deletion mutations were more stable than substitution mutations. And as discussed above, the success in making one type of mutation at position 51 gave a reasonable expectation of success in making another type of mutation at position 51. Therefore it is maintained that motivation and reasonable expectation of success were both present prior to applicant's invention. Similar to Dillon, Applicant has not shown that the claimed mutant possesses unexpectedly improved properties or properties lacking in the prior art substitution mutations. Therefore applicant's argument of unexpected results is not sufficient to overcome the previous conclusion of prima facie obviousness for the invention as a whole.

Claims 4-6, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitt et al US2005/0260601 as applied to claim 3 above, and further in view of Desforges et al (Virus Research 76:87-102, 2001, cited in IDS), for reasons of record. Applicant's arguments on the deficiencies of Whitt are addressed above.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/  
Primary Examiner, Art Unit 1648

1/16/09